Attorney Docket No.: PB60557USw

# **Amendments to the Specification:**

On page 1, after the Title, please add, on its own line, the following heading paragraph, and subsequent heading:

## CROSS-REFERENCE TO RELATED APPLICATIONS

This application is filed pursuant to 35 U.S.C. § 371 as a United States National Phase Application of International Application No. PCT/EP2004/011963 filed October 21, 2004, which claims priority from GB0324886.1 filed October 24, 2003.

### FIELD OF THE INVENTION

On page 1, line 9, please add, on its own line, the following heading:

### BACKGROUND OF THE INVENTION

On page 1, line 22, please add, on its own line, the following heading:

## SUMMARY OF THE INVENTION

On page 9, line 13 please add, on its own line, the following heading:

#### **DETAILED DESCRIPTION**

On page 18, line 4, please delete the paragraph beginning with "Each capsule or cartridge may ..." and replace it with the following replacement paragraph.

Each capsule or cartridge may generally contain between 20μg-10mg of the compound of formula (I) optionally in combination with another therapeutically active ingredient. Alternatively, the compound of the invention may be presented without excipients. Packaging of the formulation may be suitable for

unit dose or multi-dose delivery. In the case of multi-dose delivery, the formulation can be pre-metered (eg as in Diskus, see GB 2242134, US Patent Nos. 6,632,666, 5,860,419, 5,873,360 and 5,590,645 or Diskhaler, see GB 2178965, 2129691 and 2169265, US Patent No.s 4,778,054, 4,811,731, 5,035,237, the disclosures of which are hereby incorporated by reference) or metered in use (eg as in Turbuhaler, see EP 69715 or in the devices described in US Patents No. 6,321,747 the disclosures of which are hereby incorporated by reference). An example of a unit-dose device is Rotahaler (see GB 2064336 and US Patent No. 4,353,656 4,353,365, the disclosures of which are hereby incorporated by reference). The Diskus inhalation device comprises an elongate strip formed from a base sheet having a plurality of recesses spaced along its length and a lid sheet hermetically but peelably sealed thereto to define a plurality of containers, each container having therein an inhalable formulation containing a compound of formula (I) preferably combined with lactose. Preferably, the strip is sufficiently flexible to be wound into a roll. The lid sheet and base sheet will preferably have leading end portions which are not sealed to one another and at least one of the said leading end portions is constructed to be attached to a winding means. Also, preferably the hermetic seal between the base and lid sheets extends over their whole width. The lid sheet may preferably be peeled from the base sheet in a longitudinal direction from a first end of the said base sheet.

On page 22, line 1, please delete the paragraph beginning with "A method for determining ..." and replace it with the following replacement paragraph.

A method for determining IC<sub>50</sub> ratios is set out in US patent 5,998,428 which is incorporated herein in full by reference as though set out herein. See also PCT application  $\frac{\text{WO } 00/57599}{\text{WO } 00/51599}$  for another description of said assay.